UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

UMB BANK, N.A., as Trustee, Plaintiff, v. SANOFI, Defendant.	Case No. 15 Civ. 8725 (GBD) (JCF) ECF CASE

ANSWER TO THE SECOND AMENDED COMPLAINT

Sanofi, through its undersigned attorneys, for its Answer to the Second Amended Complaint (the "Second Amended Complaint"), responds as follows.[1]

With respect to the Second Amended Complaint in its entirety, Sanofi denies that it engaged in any wrongful, illegal or improper conduct, or caused or is responsible in any way for any injuries or damages purportedly suffered by Plaintiff or any holder of contingent value rights (collectively, "CVR Holders," and each a "CVR Holder"). Nothing herein is intended to waive or otherwise controvert: (i) the partial dismissal of the Complaint as provided in the Court's Memorandum Decision and Order dated September 8, 2016 (the "September Order"); or (ii) the denial of Plaintiff's Motion for Partial Summary Judgment as also provided in the September Order.

[1] To the extent any of the Second Amended Complaint's headings or titles contain substantive allegations, Sanofi denies those allegations. References herein to paragraphs of the Second Amended Complaint expressly include any footnotes contained in such paragraphs. With respect to footnotes 1 and 2 of the Second Amended Complaint, which are not contained in any numbered paragraph of the Second Amended Complaint, Sanofi responds as follows: Admits that Plaintiff UMB Bank, N.A. ("Plaintiff") filed a Supplemental Complaint (ECF No. 52), and that, on July 19, 2016, the Court granted Plaintiff's unopposed motion to substitute UMB Bank, N.A., as Trustee, for then Plaintiff American Stock Transfer & Trust Company, LLC; refers to Sanofi's Answer to the Supplemental Complaint (ECF No. 64) and the Contingent Value Rights Agreement by and between Sanofi-Aventis and American Stock Transfer & Trust Company, LLC, dated as of March 30, 2011 (the "CVR Agreement") for a complete and accurate description of their contents; and otherwise denies the allegations contained in footnotes 1 and 2 of the Second Amended Complaint.

1. Admits that Genzyme Corporation ("Genzyme") is a global biotechnology company, that Sanofi acquired Genzyme in 2011, that, in connection with Sanofi's acquisition of Genzyme, Genzyme stockholders received one publicly-traded contingent value right ("CVR") and $74.00 in cash for each Genzyme share, and that the terms of the CVRs are set forth in the CVR Agreement; and otherwise denies the allegations contained in Paragraph 1 of the Second Amended Complaint.

2. Admits that Genzyme did not accept Sanofi's first offer to acquire it; and otherwise denies the allegations contained in Paragraph 2 of that Second Amended Complaint.

3. Admits that Genzyme is a global biotechnology company, that Sanofi entered into a merger agreement with Genzyme dated as of February 16, 2011, and that Sanofi completed its acquisition of Genzyme on or about April 8, 2011; and otherwise denies the allegations contained in Paragraph 3 of the Second Amended Complaint.

4. Admits that Sanofi and Genzyme entered into a definitive merger agreement pursuant to which Sanofi would acquire Genzyme for $74.00 in cash and one CVR per Genzyme share, that the CVRs are publicly-traded on the NASDAQ and that UMB is a successor Trustee; refers to the Schedule 14D-9 filed by Genzyme with the United States Securities and Exchange Commission (the "SEC") on March 7, 2011 and the CVR Agreement for a complete and accurate description of their contents; and otherwise denies the allegations contained in Paragraph 4 of the Second Amended Complaint.

5. Refers to the CVR Agreement for a complete and accurate description of its contents; avers that to the extent the allegations contained in Paragraph 5 of the Second Amended Complaint relate to claims and/or theories that have been dismissed by the Court, no

response is required to such allegations; and otherwise denies the allegations contained in Paragraph 5.

6. Refers to the CVR Agreement for a complete and accurate description of its contents; avers that to the extent the allegations contained in Paragraph 6 of the Second Amended Complaint relate to claims and/or theories that have been dismissed by the Court, no response is required to such allegations; and otherwise denies the allegations contained in Paragraph 6.

7. Refers to the CVR Agreement for a complete and accurate description of its contents; and otherwise denies the allegations contained in Paragraph 7 of the Second Amended Complaint.

8. Avers that to the extent the allegations contained in Paragraph 8 of the Second Amended Complaint relate to claims and/or theories that have been dismissed by the Court, no response is required; and otherwise denies the allegations contained in Paragraph 8.

9. Denies knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 9 of the Second Amended Complaint.

10. Admits that Plaintiff purports to bring this action under the cited provisions of the CVR Agreement, and that, on July 19, 2016, the Court granted Plaintiff's unopposed motion to substitute UMB Bank, N.A., as Trustee, for then Plaintiff American Stock Transfer & Trust Company, LLC; refers to the CVR Agreement for a complete and accurate description of its contents; and otherwise denies knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 10 of the Second Amended Complaint.

11. Admits the allegations contained in the first sentence of Paragraph 11 of the Second Amended Complaint, that Sanofi is a global pharmaceutical company, and that Genzyme is a wholly-owned subsidiary of Sanofi; refers to the CVR Agreement for a complete and accurate description of its contents; and otherwise denies the allegations contained in Paragraph 11.

12. Admits that Plaintiff purports to base jurisdiction over the subject matter of this action on the statutory provision cited; and otherwise avers that the allegations contained in Paragraph 12 of the Second Amended Complaint constitute legal conclusions to which no response is required.

13. Admits that Plaintiff purports to base venue on the statutory provision cited; and otherwise avers that the allegations contained in Paragraph 13 of the Second Amended Complaint constitute legal conclusions to which no response is required.

14. Refers to the CVR Agreement for a complete and accurate description of its contents; and otherwise denies the allegations contained in Paragraph 14 of the Second Amended Complaint.

15. Admits that Sanofi received a "written notice" on or before August 7, 2015; refers to the "written notice" for a complete and accurate description of its contents; and otherwise denies the allegations contained in Paragraph 15 of the Second Amended Complaint.

16. Refers to the CVR Agreement for a complete and accurate description of its contents; avers that to the extent the allegations contained in Paragraph 16 of the Second Amended Complaint relate to claims and/or theories that have been dismissed by the Court, no response is required to such allegations; and otherwise denies the allegations contained in Paragraph 16.

17. Refers to the CVR Agreement for a complete and accurate description of its contents; avers that to the extent the allegations contained in Paragraph 17 of the Second Amended Complaint relate to claims and/or theories that have been dismissed by the Court, no response is required to such allegations; and otherwise denies the allegations contained in Paragraph 17.

18. Admits that Sanofi did not achieve the Approval Milestone or Product Sales Milestone #1 (both as defined in the CVR Agreement), avers that to the extent the allegations contained in Paragraph 18 of the Second Amended Complaint relate to claims and/or theories that have been dismissed by the Court, no response is required to such allegations; and otherwise denies the allegations contained in Paragraph 18.

19. Avers that to the extent the allegations contained in Paragraph 19 of the Second Amended Complaint relate to claims and/or theories that have been dismissed by the Court, no response is required to such allegations; and otherwise denies the allegations contained in Paragraph 19.

20. Denies the allegations contained in Paragraph 20 of the Second Amended Complaint.

21. Avers that to the extent the allegations contained in Paragraph 21 of the Second Amended Complaint relate to claims and/or theories that have been dismissed by the Court, no response is required to such allegations; and otherwise denies the allegations contained in Paragraph 21.

22. Avers that to the extent the allegations contained in Paragraph 22 of the Second Amended Complaint relate to claims and/or theories that have been dismissed by the

Court, no response is required to such allegations; and otherwise denies the allegations contained in Paragraph 22.

23. Avers that to the extent the allegations contained in Paragraph 23 of the Second Amended Complaint relate to claims and/or theories that have been dismissed by the Court, no response is required to such allegations; and otherwise denies the allegations contained in Paragraph 23.

24. Refers to the CVR Agreement and the written correspondence between the parties for a complete and accurate description of their contents; avers that to the extent the allegations contained in Paragraph 24 of the Second Amended Complaint relate to claims and/or theories that have been dismissed by the Court, no response is required to such allegations; and otherwise denies the allegations contained in Paragraph 24.

25. Refers to the CVR Agreement and the written correspondence between the parties for a complete and accurate description of their contents; and otherwise denies the allegations contained in Paragraph 25 of the Second Amended Complaint.

26. Avers that to the extent the allegations contained in Paragraph 26 of the Second Amended Complaint relate to claims and/or theories that have been dismissed by the Court, no response is required to such allegations; and otherwise denies the allegations contained in Paragraph 26.

27. Refers to the CVR Agreement for a complete and accurate description of its contents; avers that to the extent the allegations contained in Paragraph 27 of the Second Amended Complaint relate to claims and/or theories that have been dismissed by the Court, no response is required to such allegations; and otherwise denies the allegations contained in Paragraph 27.

28. Admits that Sanofi did not achieve the Approval Milestone, Product Sales Milestone #1 or the Production Milestone (each as defined in the CVR Agreement) and, thus, had no obligation to make any corresponding payments; avers that to the extent the allegations contained in Paragraph 28 of the Second Amended Complaint relate to claims and/or theories that have been dismissed by the Court, no response is required to such allegations; and otherwise denies the allegations contained in Paragraph 28.

29. Refers to the CVR Agreement for a complete and accurate description of its contents; avers that to the extent the allegations contained in Paragraph 29 of the Second Amended Complaint relate to claims and/or theories that have been dismissed by the Court, no response is required to such allegations; and otherwise denies the allegations contained in Paragraph 29.

30. Refers to the CVR Agreement for a complete and accurate description of its contents; and otherwise denies the allegations contained in Paragraph 30 of the Second Amended Complaint.

31. Refers to the CVR Agreement for a complete and accurate description of its contents; and otherwise denies the allegations contained in Paragraph 31 of the Second Amended Complaint.

32. Refers to the CVR Agreement for a complete and accurate description of its contents; avers that to the extent the allegations contained in Paragraph 32 of the Second Amended Complaint relate to claims and/or theories that have been dismissed by the Court, no response is required to such allegations; and otherwise denies the allegations contained in Paragraph 32.

33. Admits that Genzyme entered into a License and Asset Purchase Agreement with Bayer, dated as of March 30, 2009 (the "LAPA"); refers to the LAPA for a complete and accurate description of its contents; and otherwise denies the allegations contained in Paragraph 33 of the Second Amended Complaint.

34. Refers to the LAPA for a complete and accurate description of its contents; and otherwise denies the allegations contained in Paragraph 34 of the Second Amended Complaint.

35. Refers to the Form 20-F Sanofi filed with the SEC on March 11, 2015 for a complete and accurate description of Sanofi's financial assets and liabilities measured at fair value; and otherwise denies the allegations contained in Paragraph 35 of the Second Amended Complaint.

36. Refers to the CVR Agreement for a complete and accurate description of its contents; avers that to the extent the allegations contained in Paragraph 36 of the Second Amended Complaint relate to claims and/or theories that have been dismissed by the Court, no response is required to such allegations; and otherwise denies the allegations contained in Paragraph 36.

37. Refers to the CVR Agreement for a complete and accurate description of its contents; avers that to the extent the allegations contained in Paragraph 37 of the Second Amended Complaint relate to claims and/or theories that have been dismissed by the Court, no response is required to such allegations; and otherwise denies the allegations contained in Paragraph 37.

38. Refers to the CVR Agreement for a complete and accurate description of its contents; and otherwise denies the allegations contained in Paragraph 38 of the Second Amended Complaint.

39. Refers to the CVR Agreement for a complete and accurate description of its contents; and otherwise denies the allegations contained in Paragraph 39 of the Second Amended Complaint.

40. Refers to the CVR Agreement for a complete and accurate description of its contents; and otherwise denies the allegations contained in Paragraph 40 of the Second Amended Complaint.

41. Refers to the CVR Agreement for a complete and accurate description of its contents; and otherwise denies the allegations contained in Paragraph 41 of the Second Amended Complaint.

42. Refers to the CVR Agreement for a complete and accurate description of its contents; and otherwise denies the allegations contained in Paragraph 42 of the Second Amended Complaint.

43. Refers to 21 C.F.R. § 601.20 for a complete and accurate description of its contents; and otherwise denies the allegations contained in Paragraph 43 of the Second Amended Complaint.

44. Refers to 21 C.F.R. § 314.126 for a complete and accurate description of its contents; and otherwise denies the allegations contained in Paragraph 44 of the Second Amended Complaint.

45. Admits that, in May 2001, the FDA issued Department of Health and Human Services U.S. License No. 1289, which license authorized the introduction into interstate

commerce of alemtuzumab for the treatment of patients with B-cell chronic lymphocytic leukemia; and otherwise denies the allegations contained in Paragraph 45 of the Second Amended Complaint.

46. Admits that Genzyme conducted Phase II and Phase III clinical trials studying alemtuzumab (Lemtrada™) for the treatment of multiple sclerosis and that Genzyme and the FDA engaged in communications, including, but not limited to, communications relating to the design of the clinical trials; and otherwise denies the allegations contained in Paragraph 46 of the Second Amended Complaint.

47. Admits that a double-blinded study is a study in which both subjects and investigators generally are unaware of each subject's assigned treatment; and otherwise denies the allegations contained in Paragraph 47 of the Second Amended Complaint.

48. Admits that Genzyme used an open-label, rater-blind design in connection with the Lemtrada Phase III clinical trials, that an "open-label" study design generally means both the subject and/or treating physician know which treatment is being provided, and that an "open-label, rater-blind" design generally means both the subject and/or treating physician know which treatment is being provided, but the rater analyzing the subjects does not; and otherwise denies the allegations contained in Paragraph 48 of the Second Amended Complaint.

49. Admits that, on June 12, 2012, Genzyme announced in a press release (the "June 12, 2012 Press Release") that it had submitted a supplemental Biologics License Application (the "sBLA") to the FDA seeking approval of alemtuzumab (Lemtrada™) for the treatment of multiple sclerosis; refers to the June 12, 2012 Press Release for a complete and accurate description of its contents; and otherwise denies the allegations contained in Paragraph 49 of the Second Amended Complaint.

50. Admits that the FDA issued a Refuse to File letter in August 2012 (the "Refuse to File Letter"), and that Genzyme announced the receipt of the Refuse to File Letter in a press release dated August 27, 2012 (the "August 27, 2012 Press Release"); refers to the Refuse to File Letter and the August 27, 2012 Press Release for a complete and accurate description of their contents; and otherwise denies the allegations contained in Paragraph 50 of the Second Amended Complaint.

51. Admits that Genzyme submitted a revised sBLA on November 27, 2012 and that the FDA accepted the revised sBLA for review in January 2013; and otherwise denies the allegations contained in Paragraph 51 of the Second Amended Complaint.

52. Admits that the FDA issued a complete response letter on December 27, 2013 (the "Complete Response Letter") and that Genzyme announced the receipt of the Complete Response Letter in a press release dated December 30, 2013 (the "December 30, 2013 Press Release"); refers to the Complete Response Letter and the December 30, 2013 Press Release for a complete and accurate description of their contents; and otherwise denies the allegations contained in Paragraph 52 of the Second Amended Complaint.

53. Admits that Genzyme issued a press release on April 7, 2014 (the "April 7 Press Release"); refers to the April 7, 2014 Press Release for a complete and accurate description of its contents; and otherwise denies the allegations contained in Paragraph 53 of the Second Amended Complaint.

54. Admits that Genzyme filed an amendment to the sBLA on or about April 15, 2014 and that between April 2014 and November 2014, Genzyme submitted 32 amendments to the sBLA; and otherwise denies the allegations contained in Paragraph 54 of the Second Amended Complaint.

55. Admits that the FDA approved Lemtrada by letter dated November 14, 2014 (the "November 2014 Letter"); refers to the November 2014 Letter for a complete and accurate description of its contents; and otherwise denies the allegations contained in Paragraph 55 of the Second Amended Complaint.

56. Denies knowledge or information sufficient to form a belief as to the truth of the allegations regarding the "FDA's standard time period;" and otherwise denies the allegations contained in Paragraph 56 of the Second Amended Complaint.

57. Admits that, in May 2015, Sanofi signed an agreement with Retrophin, Inc. to acquire a Rare Pediatric Disease Priority Review Voucher for total consideration of $245 million, and that a Priority Review Voucher was not obtained in connection with Lemtrada; refers to 21 U.S.C. § 360ff for the definition of the terms "priority review" and "priority review voucher;" and otherwise denies the allegations contained in Paragraph 57.

58. Denies the allegations contained in Paragraph 58 of the Second Amended Complaint.

59. Denies the allegations contained in Paragraph 59 of the Second Amended Complaint.

60. Denies the allegations contained in Paragraph 60 of the Second Amended Complaint.

61. Admits that the Lemtrada Phase III clinical trials were designed as "open-label, rater-blind" studies and that Rebif® (interferon beta-l a) was used as an active comparator in the Phase III clinical studies; and otherwise denies the allegations contained in Paragraph 61 of the Second Amended Complaint.

62. Avers that Lemtrada was approved by the FDA on November 14, 2014; and otherwise denies the allegations contained in Paragraph 62 of the Second Amended Complaint.

63. Denies the allegations contained in Paragraph 63 of the Second Amended Complaint.

64. Admits that, in November 2013, the FDA released briefing materials (the "Briefing Materials") in advance of the November 13, 2013 FDA Peripheral and Central Nervous System Drugs Advisory Committee (the "Advisory Committee") meeting; and otherwise denies the allegations contained in Paragraph 64 of the Second Amended Complaint.

65. Refers to the Briefing Materials for a complete and accurate description of their contents; and otherwise denies the allegations contained in Paragraph 65 of the Second Amended Complaint.

66. Refers to the transcript of the November 13, 2013 Advisory Committee meeting (the "Advisory Committee Transcript") for a complete and accurate description of its contents; and otherwise denies the allegations contained in Paragraph 66 of the Second Amended Complaint.

67. Refers to the sBLA (including its amendments) for a complete and accurate description of its contents; and otherwise denies the allegations contained in Paragraph 67 of the Second Amended Complaint.

68. Refers to the Advisory Committee Transcript and the sBLA (including its amendments) for a complete and accurate description of their contents; and otherwise denies the allegations contained in Paragraph 68 of the Second Amended Complaint.

69. Refers to the Advisory Committee Transcript and the sBLA (including its amendments) for a complete and accurate description of their contents; and otherwise denies the allegations contained in Paragraph 69 of the Second Amended Complaint.

70. Refers to the Advisory Committee Transcript and the sBLA (including its amendments) for a complete and accurate description of their contents; denies knowledge or information sufficient to form a belief as to the truth of the allegations contained in the fourth sentence of Paragraph 70 of the Second Amended Complaint; and otherwise denies the allegations contained in Paragraph 70.

71. Admits that baseline information generally is gathered at the beginning of a study, against which variations in the study are measured; refers to the Advisory Committee Transcript and the sBLA (including its amendments) for a complete and accurate description of their contents; and otherwise denies the allegations contained in Paragraph 71 of the Second Amended Complaint.

72. Admits that EDSS refers to the Kurtzke Expanded Disability Status Scale; refers to the Advisory Committee Transcript and the sBLA (including its amendments) for a complete and accurate description of their contents; and otherwise denies the allegations contained in Paragraph 72 of the Second Amended Complaint.

73. Refers to the Advisory Committee Transcript and the sBLA (including its amendments) for a complete and accurate description of their contents; and otherwise denies the allegations contained in Paragraph 73 of the Second Amended Complaint.

74. Refers to the Advisory Committee Transcript and the sBLA (including its amendments) for a complete and accurate description of their contents; and otherwise denies the allegations contained in Paragraph 74 of the Second Amended Complaint.

75. Refers to the Briefing Materials for a complete and accurate description of their contents; and otherwise denies the allegations contained in Paragraph 75 of the Second Amended Complaint.

76. Refers to the Advisory Committee Transcript for a complete and accurate description of its contents; and otherwise denies the allegations contained in Paragraph 76 of the Second Amended Complaint.

77. Denies the allegations contained in Paragraph 77 of the Second Amended Complaint.

78. Denies the allegations contained in Paragraph 78 of the Second Amended Complaint.

79. Admits that a "double-blind" study generally refers to a study in which both subjects and investigators generally are unaware of each subject's assigned treatment; denies knowledge or information sufficient to form a belief as to the truth of the allegations regarding the Roche Double-Blind MS Studies involving a drug called "ocrelizumab;" and otherwise denies the allegations contained in Paragraph 79 of the Second Amended Complaint.

80. Refers to the FDA's Prescribing Information for the recommended administration of Lemtrada and Rebif; denies knowledge or information sufficient to form a belief as to the truth of the allegations regarding the Roche Double-Blind MS Studies involving a drug called "ocrelizumab;" and otherwise denies the allegations contained in Paragraph 80 of the Second Amended Complaint.

81. Denies knowledge or information sufficient to form a belief as to the truth of the allegations regarding the Roche Double-Blind MS Studies involving a drug called

"ocrelizumab;" and otherwise denies the allegations contained in Paragraph 81 of the Second Amended Complaint.

82. Denies the allegations contained in Paragraph 82 of the Second Amended Complaint.

83. Refers to the Advisory Committee Transcript for a complete and accurate description of its contents; and otherwise denies the allegations contained in Paragraph 83 of the Second Amended Complaint.

84. Denies the allegations contained in Paragraph 84 of the Second Amended Complaint.

85. Denies the allegations contained in Paragraph 85 of the Second Amended Complaint.

86. Admits that the FDA issued the Complete Response Letter; refers to the Complete Response Letter for a complete and accurate description of its contents; and otherwise denies the allegations contained in Paragraph 86 of the Second Amended Complaint.

87. Admits that the Approval Milestone (as defined in the CVR Agreement) had a deadline of March 31, 2014 and that Genzyme submitted 32 amendments to the sBLA during the time period April 2014 through November 2014; refers to the sBLA (including its amendments) for a complete and accurate description of its contents; and otherwise denies the allegations contained in Paragraph 87 of the Second Amended Complaint.

88. Admits that the FDA approved Lemtrada on November 14, 2014; refers to the sBLA (including its amendments) for a complete and accurate description of its contents; and otherwise denies the allegations contained in Paragraph 88 of the Second Amended Complaint.

89. Refers to the transcript of Sanofi's October 28, 2014 earnings call for a complete and accurate description of its contents; avers that to the extent the allegations contained in Paragraph 89 of the Second Amended Complaint relate to claims and/or theories that have been dismissed by the Court, no response is required to such allegations; and otherwise denies the allegations contained in Paragraph 89 of the Second Amended Complaint.

90. Refers to the sBLA (including its amendments) and the Briefing Materials for a complete and accurate description of their contents; and otherwise denies the allegations contained in Paragraph 90 of the Second Amended Complaint.

91. Refers to the Advisory Committee Transcript for a complete and accurate description of its contents; and otherwise denies the allegations contained in Paragraph 91 of the Second Amended Complaint.

92. Admits that the FDA required that Lemtrada's label state that "the use of LEMTRADA should generally be reserved for patients who have had an inadequate response to two or more drugs indicated for the treatment of MS;" and otherwise denies the allegations contained in Paragraph 92 of the Second Amended Complaint.

93. Admits that the FDA required a Risk Evaluation and Mitigation Strategy ("REMS") for Lemtrada; refers to 21 U.S.C. § 355-1 for a complete and accurate description of the use of a REMS program; and otherwise denies the allegations contained in Paragraph 93 of the Second Amended Complaint.

94. Denies the allegations contained in Paragraph 94 of the Second Amended Complaint.

95. Avers that to the extent the allegations contained in Paragraph 95 of the Second Amended Complaint relate to claims and/or theories that have been dismissed by the

Court, no response is required to such allegations; and otherwise denies the allegations contained in Paragraph 95.

96. Avers that to the extent the allegations contained in Paragraph 96 of the Second Amended Complaint relate to claims and/or theories that have been dismissed by the Court, no response is required to such allegations; and otherwise denies the allegations contained in Paragraph 96.

97. Avers that to the extent the allegations contained in Paragraph 97 of the Second Amended Complaint relate to claims and/or theories that have been dismissed by the Court, no response is required to such allegations; and otherwise denies the allegations contained in Paragraph 97.

98. Avers that to the extent the allegations contained in Paragraph 98 of the Second Amended Complaint relate to claims and/or theories that have been dismissed by the Court, no response is required to such allegations; and otherwise denies the allegations contained in Paragraph 98.

99. Admits that Sanofi did not achieve Product Sales Milestone #1; refers to the Forms 6-K Sanofi filed with the SEC on October 29, 2015, July 5, 2016 and July 29, 2016 for a complete and accurate description of their contents; and otherwise denies the allegations contained in Paragraph 99 of the Second Amended Complaint.

100. Avers that to the extent the allegations contained in Paragraph 100 of the Second Amended Complaint relate to claims and/or theories that have been dismissed by the Court, no response is required to such allegations; and otherwise denies the allegations contained in Paragraph 100.

101. Refers to the CVR Agreement and the LAPA for a complete and accurate description of their contents; admits that Sanofi is not obligated to make any contingent payments as a result of the regulatory approval or sales of Aubagio®; avers that to the extent the allegations contained in Paragraph 101 of the Second Amended Complaint relate to claims and/or theories that have been dismissed by the Court, no response is required to such allegations; and otherwise denies the allegations contained in Paragraph 101.

102. Avers that to the extent the allegations contained in Paragraph 102 of the Second Amended Complaint relate to claims and/or theories that have been dismissed by the Court, no response is required to such allegations; and otherwise denies the allegations contained in Paragraph 102.

103. Admits that Sanofi submitted a New Drug Application to the FDA on August 12, 2011 for Aubagio® (teriflunomide) (the "NDA") and that the FDA approved the NDA on September 12, 2012; avers that to the extent the allegations contained in Paragraph 103 of the Second Amended Complaint relate to claims and/or theories that have been dismissed by the Court, no response is required to such allegations; and otherwise denies the allegations contained in Paragraph 103.

104. Refers to the article quoted and the transcript of Genzyme's July 30, 2015 earnings call for a complete and accurate description of their contents; avers that to the extent the allegations contained in Paragraph 104 of the Second Amended Complaint relate to claims and/or theories that have been dismissed by the Court, no response is required to such allegations; and otherwise denies the allegations contained in Paragraph 104.

105. Avers that to the extent the allegations contained in Paragraph 105 of the Second Amended Complaint relate to claims and/or theories that have been dismissed by the

Court, no response is required to such allegations; and otherwise denies the allegations contained in Paragraph 105.

106. Refers to the website cited in Paragraph 106 of the Second Amended Complaint for a complete and accurate description of its contents; avers that to the extent the allegations contained in Paragraph 106 relate to claims and/or theories that have been dismissed by the Court, no response is required to such allegations; and otherwise denies the allegations contained in Paragraph 106.

107. Refers to the website cited in Paragraph 107 of the Second Amended Complaint for a complete and accurate description of its contents; avers that to the extent the allegations contained in Paragraph 107 relate to claims and/or theories that have been dismissed by the Court, no response is required to such allegations; and otherwise denies the allegations contained in Paragraph 107.

108. Refers to the website cited in Paragraph 108 of the Second Amended Complaint for a complete and accurate description of its contents; avers that to the extent the allegations contained in Paragraph 108 relate to claims and/or theories that have been dismissed by the Court, no response is required to such allegations; and otherwise denies the allegations contained in Paragraph 108.

109. Refers to the Form 6-K Sanofi filed with the SEC on January 29, 2013 and the transcript of Sanofi's February 5, 2015 earnings call for a complete and accurate description of their contents; and otherwise denies the allegations contained in Paragraph 109 of the Second Amended Complaint.

110. Admits that Sanofi submitted the NDA on August 12, 2011, that the FDA approved the NDA on September 12, 2012, that Sanofi reported €7 million of net sales of

Aubagio® (teriflunomide) for the year ended December 31, 2012, that Sanofi reported €166 million of net sales of Aubagio® (teriflunomide) for the year ended December 31, 2013, that Genzyme announced on June 12, 2012 that it had submitted the sBLA to the FDA, that the FDA approved the sBLA on November 14, 2014, that Sanofi reported €2 million of net sales of Lemtrada for the year ended December 31, 2013, that Sanofi reported €34 million of net sales of Lemtrada for the year ended December 31, 2014, and that Sanofi reported €94 million of net sales of Lemtrada for the two quarters ended June 30, 2015; and otherwise denies the allegations contained in Paragraph 110 of the Second Amended Complaint.

111. Avers that to the extent the allegations contained in Paragraph 111 of the Second Amended Complaint relate to claims and/or theories that have been dismissed by the Court, no response is required to such allegations; and otherwise denies the allegations contained in Paragraph 111.

112. Avers that to the extent the allegations contained in Paragraph 112 of the Second Amended Complaint relate to claims and/or theories that have been dismissed by the Court, no response is required to such allegations; and otherwise denies the allegations contained in Paragraph 112.

113. Admits that Sanofi reported sales of Lemtrada in the United States, the United Kingdom and Germany as of December 31, 2014; refers to Genzyme's February 4, 2014 press release and the CVR Agreement for a complete and accurate description of their contents; avers that to the extent the allegations contained in Paragraph 113 of the Second Amended Complaint relate to claims and/or theories that have been dismissed by the Court, no response is required to such allegations; and otherwise denies the allegations contained in Paragraph 113.

114. Admits that, as of the date of the filing of the Second Amended Complaint, there has been no First Commercial Sale (as defined in the CVR Agreement) in France; refers to the CVR Agreement for a complete and accurate description of its contents; avers that to the extent the allegations contained in Paragraph 114 of the Second Amended Complaint relate to claims and/or theories that have been dismissed by the Court, no response is required to such allegations; and otherwise denies the allegations contained in Paragraph 114.

115. Refers to the transcript of Sanofi's October 29, 2015 earnings call for a complete and accurate description of its contents; and otherwise denies the allegations contained in Paragraph 115 of the Second Amended Complaint.

116. Refers to the CVR Agreement for a complete and accurate description of its contents; and otherwise denies the allegations contained in Paragraph 116 of the Second Amended Complaint.

117. Admits that U.S. Patent No. 6,120,766 was issued on September 19, 2000; refers to U.S. Patent No. 6,120,766 for a complete and accurate description of its contents; and otherwise denies the allegations contained in Paragraph 117 of the Second Amended Complaint.

118. Avers that the allegations contained in the first sentence of Paragraph 118 of the Second Amended Complaint constitute a legal conclusion to which no response is required; and otherwise denies the allegations contained in Paragraph 118.

119. Refers to U.S. Patent No. 6,120,766 for a complete and accurate description of its contents; avers that to the extent the allegations contained in Paragraph 119 of the Second Amended Complaint constitute a legal conclusion or relate to claims and/or theories that have been dismissed by the Court, no response is required to such allegations; and otherwise denies the allegations contained in Paragraph 119.

120. Avers that to the extent the allegations contained in Paragraph 120 relate to claims and/or theories that have been dismissed by the Court, no response is required to such allegations; and otherwise denies knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 120 of the Second Amended Complaint.

121. Avers that to the extent the allegations contained in Paragraph 121 of the Second Amended Complaint relate to claims and/or theories that have been dismissed by the Court, no response is required to such allegations; and otherwise denies the allegations contained in Paragraph 121.

122. Avers that to the extent the allegations contained in Paragraph 122 of the Second Amended Complaint relate to claims and/or theories that have been dismissed by the Court, no response is required to such allegations; and otherwise denies the allegations contained in Paragraph 122.

123. Avers that to the extent the allegations contained in Paragraph 123 of the Second Amended Complaint relate to claims and/or theories that have been dismissed by the Court, no response is required to such allegations; and otherwise denies the allegations contained in Paragraph 123.

124. Refers to the CVR Agreement for a complete and accurate description of its contents; avers that to the extent the allegations contained in Paragraph 124 of the Second Amended Complaint relate to claims and/or theories that have been dismissed by the Court, no response is required to such allegations; and otherwise denies the allegations contained in Paragraph 124.

125. Refers to the CVR Agreement and the LAPA for a complete and accurate description of their contents; avers that to the extent the allegations contained in Paragraph 125

of the Second Amended Complaint relate to claims and/or theories that have been dismissed by the Court, no response is required to such allegations; and otherwise denies the allegations contained in Paragraph 125.

126. Avers that Count III of the Second Amended Complaint, for Sanofi's alleged breach of the implied covenant of good faith and fair dealing, was dismissed by the Court and, thus, no response to the allegations contained in Paragraph 126 of the Second Amended Complaint is required (to the extent a response is required, Sanofi denies such allegations).

127. Avers that Count III of the Second Amended Complaint, for Sanofi's alleged breach of the implied covenant of good faith and fair dealing, was dismissed by the Court and, thus, no response to the allegations contained in Paragraph 127 of the Second Amended Complaint is required (to the extent a response is required, Sanofi denies such allegations).

128. Avers that Count III of the Second Amended Complaint, for Sanofi's alleged breach of the implied covenant of good faith and fair dealing, was dismissed by the Court and, thus, no response to the allegations contained in Paragraph 128 of the Second Amended Complaint is required (to the extent a response is required, Sanofi denies such allegations).

129. Avers that Count III of the Second Amended Complaint, for Sanofi's alleged breach of the implied covenant of good faith and fair dealing, was dismissed by the Court and, thus, no response to the allegations contained in Paragraph 129 of the Second Amended Complaint is required (to the extent a response is required, Sanofi denies such allegations).

130. Avers that Count III of the Second Amended Complaint, for Sanofi's alleged breach of the implied covenant of good faith and fair dealing, was dismissed by the Court and, thus, no response to the allegations contained in Paragraph 130 of the Second Amended Complaint is required (to the extent a response is required, Sanofi denies such allegations).

131. Refers to the CVR Agreement for a complete and accurate description of its contents; and otherwise denies the allegations contained in Paragraph 131 of the Second Amended Complaint.

132. Denies the allegations contained in Paragraph 132 of the Second Amended Complaint.

133. Denies the allegations contained in Paragraph 133 of the Second Amended Complaint.

134. Admits that the Production Milestone (as defined in the CVR Agreement) was not met and, thus, Sanofi had no obligation to make any corresponding payment; and otherwise denies the allegations contained in Paragraph 134 of the Second Amended Complaint.

135. Admits that the Production Milestone (as defined in the CVR Agreement) was not met and, thus, Sanofi had no obligation to make any corresponding payment, that Sanofi reported €633,000,000 of net sales of Cerezyme® for the year ended December 31, 2012, and that Sanofi reported €292,000,000 of net sales of Fabrazyme® for the year ended December 31, 2012; and otherwise denies the allegations contained in Paragraph 135 of the Second Amended Complaint.

136. Admits that Sanofi reported sales growth of 22.5% for New Genzyme for the quarter ended September 30, 2012, and that Sanofi reported a 7.4% decrease in business net income for the quarter ended September 30, 2012; and otherwise denies the allegations contained in Paragraph 136 of the Second Amended Complaint.

137. Admits that Genzyme has developed, in whole or part, products for the treatment of genetic diseases, including Cerezyme® and Fabrazyme®, both of which are enzyme

replacement therapies; and otherwise denies the allegations contained in Paragraph 137 of the Second Amended Complaint.

138. Admits that the FDA has promulgated regulations governing the manufacturing, processing and packing of drugs in Title 21 of the Code of Federal Regulations; refers to Title 21 of the Code of Federal Regulations for a complete and accurate description of its contents; and otherwise denies the allegations contained in Paragraph 138 of the Second Amended Complaint.

139. Admits that Gaucher Disease is a genetic disorder that affects the body's organs and tissues, the symptoms of which may vary; and otherwise denies the allegations contained in Paragraph 139 of the Second Amended Complaint.

140. Admits that Gaucher Disease results from an enzyme deficiency and that currently available treatments include enzyme replacement therapy; and otherwise denies the allegations contained in Paragraph 140 of the Second Amended Complaint.

141. Admits that imiglucerase is an analogue of the human enzyme ß-glucocerebrosidase produced by recombinant DNA technology and developed by Genzyme, that Cerezyme® is the trade name for imiglucerase, and that Cerezyme® was approved by the FDA in 1994 for the treatment of patients with Type 1 Gaucher disease; refers to the CVR Agreement for a complete and accurate description of its contents; and otherwise denies the allegations contained in Paragraph 141 of the Second Amended Complaint.

142. Admits that Fabry Disease is a genetic disorder resulting from an enzyme deficiency; and otherwise denies the allegations contained in Paragraph 142 of the Second Amended Complaint.

143. Admits that Fabry Disease is a genetic disorder that affects the body's organs and tissues, the symptoms of which may vary; and otherwise denies the allegations contained in Paragraph 143 of the Second Amended Complaint.

144. Admits that Fabrazyme® has been prescribed for the treatment of Fabry Disease; and otherwise denies the allegations contained in Paragraph 144 of the Second Amended Complaint.

145. Admits that agalsidase beta is a human α-galactosidase A enzyme with the same amino acid sequence as the native enzyme produced by recombinant DNA technology and developed by Genzyme, that Fabrazyme® is the trade name for agalsidase beta, and that Fabrazyme® was approved by the FDA in April 2003 as a treatment for patients with Fabry Disease; refers to the CVR Agreement for a complete and accurate description of its contents; and otherwise denies the allegations contained in Paragraph 145 of the Second Amended Complaint.

146. Admits that Genzyme reported revenues in excess of $1 billion in combined sales of Cerezyme® and Fabrazyme® during the years ended December 31, 2008, December 31, 2007 and December 31, 2006; and otherwise denies the allegations contained in Paragraph 146 of the Second Amended Complaint.

147. Admits that, at various times in 2009, bulk drug substance for Cerezyme® and Fabrazyme® was produced, and Cerezyme® and Fabrazyme® were fill-finished, at the Allston Facility in Framingham, Massachusetts; and otherwise denies the allegations contained in Paragraph 147 of the Second Amended Complaint.

148. Admits that bulk drug substance for Cerezyme® and Fabrazyme® was produced at the Allston Facility using bioreactors; denies knowledge or information sufficient to

form a belief as to the truth of the allegations concerning the qualities of a "classic" biotechnology production facility; and otherwise denies the allegations contained in Paragraph 148 of the Second Amended Complaint.

149. Admits that the FDA has promulgated regulations governing the manufacturing, processing and packing of drugs in Title 21 of the Code of Federal Regulations; refers to Title 21 of the Code of Federal Regulations for a complete and accurate description of its contents; and otherwise denies the allegations contained in Paragraph 149 of the Second Amended Complaint.

150. Denies the allegations contained in Paragraph 150 of the Second Amended Complaint.

151. Refers to Genzyme's 2009 Annual Report for a complete and accurate description of its contents, including regarding the bioreactor tanks at the Allston Facility; and otherwise denies the allegations contained in Paragraph 151 of the Second Amended Complaint.

152. Admits that downstream processing involves the purification of materials harvested from the cell culture manufacturing process; and otherwise denies the allegations contained in Paragraph 152 of the Second Amended Complaint.

153. Denies the allegations contained in Paragraph 153 of the Second Amended Complaint.

154. Refers to Genzyme's June 16, 2009 Press Release for a complete and accurate description of its contents; and otherwise denies the allegations contained in Paragraph 154 of the Second Amended Complaint.

155. Refers to Genzyme's July 31, 2009 Press Release and August 14, 2009 letter to the FDA for a complete and accurate description of their contents; and otherwise denies the allegations contained in Paragraph 155 of the Second Amended Complaint.

156. Admits that, as of June 25, 2009, Genzyme was in the late stages of construction on a new plant in Framingham, Massachusetts for the production of Cerezyme® and Fabrazyme®; refers to Genzyme's June 25, 2009 Press Release for a complete and accurate description of its contents; and otherwise denies the allegations contained in Paragraph 156 of the Second Amended Complaint.

157. Admits that, on May 24, 2010, Genzyme entered into a Consent Decree with the FDA regarding the Allston Facility (the "Consent Decree"); refers to the Consent Decree for a complete and accurate description of its contents; and otherwise denies the allegations contained in Paragraph 157 of the Second Amended Complaint.

158. Admits that, on February 3, 2010, Genzyme announced the hiring of Scott Canute as President of Global Manufacturing and Corporate Operations; refers to Genzyme's February 3, 2010 Press Release for a complete and accurate description of its contents; and otherwise denies the allegations contained in Paragraph 158 of the Second Amended Complaint.

159. Refers to Genzyme's February 3, 2010 Press Release for a complete and accurate description of its contents; and otherwise denies the allegations contained in Paragraph 159 of the Second Amended Complaint.

160. Admits that, on January 8, 2010, Genzyme announced the hiring of Ron Branning as Senior Vice President of Global Product Quality; refers to Genzyme's January 8, 2010 Press Release for a complete and accurate description of its contents; and otherwise denies the allegations contained in Paragraph 160 of the Second Amended Complaint.

161. Admits that, prior to joining Genzyme, Mr. Canute worked at Eli Lilly & Company for 25 years and that he and/or Genzyme recruited additional individuals to Genzyme; and otherwise denies the allegations contained in Paragraph 161 of the Second Amended Complaint.

162. Refers to the transcript of the March 31, 2010 Genzyme Corporate Manufacturing Operations Analyst and Investor Event (the "March 31 Investor Event") in which Mr. Canute participated for a complete and accurate description of its contents; and otherwise denies the allegations contained in Paragraph 162 of the Second Amended Complaint.

163. Refers to the transcript of the March 31 Investor Event for a complete and accurate description of its contents; and otherwise denies the allegations contained in Paragraph 163 of the Second Amended Complaint.

164. Refers to the transcript of the March 31 Investor Event for a complete and accurate description of its contents; and otherwise denies the allegations contained in Paragraph 164 of the Second Amended Complaint.

165. Refers to the transcript of Sanofi's April 28, 2011 investor call for a complete and accurate description of its contents; and otherwise denies the allegations contained in Paragraph 165 of the Amended Complaint.

166. Denies the allegations contained in Paragraph 166 of the Second Amended Complaint.

167. Refers to Genzyme's April 21, 2010 Press Release for a complete and accurate description of its contents; and otherwise denies the allegations contained in Paragraph 167 of the Second Amended Complaint.

168. Admits that, during the period 2010-2012, Genzyme considered continuous manufacturing technology; and otherwise denies the allegations contained in Paragraph 168 of the Second Amended Complaint.

169. Refers to Genzyme's April 21, 2010 Press Release for a complete and accurate description of its contents; and otherwise denies the allegations contained in Paragraph 169 of the Second Amended Complaint.

170. Refers to Genzyme's March 7, 2011 Schedule 14D-9 for a complete and accurate description of its contents; and otherwise denies the allegations contained in Paragraph 170 of the Second Amended Complaint.

171. Denies the allegations contained in Paragraph 171 of the Second Amended Complaint.

172. Admits that, during the week of June 28, 2010, Christopher Viehbacher called Henri Termeer to convey Sanofi's interest in a potential acquisition of Genzyme; refers to Genzyme's March 17, 2011 Schedule 14D-9 for a complete and accurate description of its contents; and otherwise denies the allegations contained in Paragraph 172 of the Second Amended Complaint.

173. Admits that, on July 29, 2010, Sanofi sent Genzyme a non-binding proposal for an acquisition of Genzyme, and that, on September 20, 2010, a meeting between Messrs. Termeer and Viehbacher took place; refers to Genzyme's March 17, 2011 Schedule 14D-9 for a complete and accurate description of its contents to the extent the allegations contained in the third and fourth sentences of Paragraph 173 of the Second Amended Complaint purport to summarize the contents thereof; and otherwise denies the allegations contained in Paragraph 173.

174. Refers to the written opinions of Genzyme's financial advisors, dated October 7, 2010, for a complete and accurate description of their contents; and otherwise denies the allegations contained in Paragraph 174 of the Second Amended Complaint.

175. Denies the allegations contained in Paragraph 175 of the Second Amended Complaint.

176. Refers to the transcript of Sanofi's August 30, 2010 investor call for a complete and accurate description of its contents; and otherwise denies the allegations contained in Paragraph 176 of the Second Amended Complaint.

177. Refers to the transcript of Sanofi's August 30, 2010 investor call for a complete and accurate description of its contents; and otherwise denies the allegations contained in Paragraph 177 of the Second Amended Complaint.

178. Refers to the transcript of the September 15, 2010 Bank of America Merrill Lynch Global Healthcare Conference for a complete and accurate description of its contents; and otherwise denies the allegations contained in Paragraph 178 of the Second Amended Complaint.

179. Refers to the October 4, 2010 letter from Mr. Viebacher to Mr. Termeer for a complete and accurate description of its contents; and otherwise denies the allegations contained in Paragraph 179 of the Second Amended Complaint.

180. Denies the allegations contained in Paragraph 180 of the Second Amended Complaint.

181. Admits that, in connection with the negotiations relating to Sanofi's acquisition of Genzyme, the parties disagreed over the value of Genzyme, including, but not limited to, the value of Genzyme's product pipeline, and that, in November 2010, the parties

began to discuss the use of a contingent value right; and otherwise denies the allegations contained in Paragraph 181 of the Second Amended Complaint.

182. Refers to the CVR Agreement for a complete and accurate description of its contents; and otherwise denies the allegations contained in Paragraph 182 of the Second Amended Complaint.

183. Admits that Sanofi and American Stock Transfer & Trust Company, LLC, the then-Trustee, executed the CVR Agreement on March 30, 2011; refers to the CVR Agreement for a complete and accurate description of its contents; and otherwise denies the allegations contained in Paragraph 183 of the Second Amended Complaint.

184. Refers to the CVR Agreement for a complete and accurate description of its contents; and otherwise denies the allegations contained in Paragraph 184 of the Second Amended Complaint.

185. Refers to the CVR Agreement for a complete and accurate description of its contents; and otherwise denies the allegations contained in Paragraph 185 of the Second Amended Complaint.

186. Refers to Genzyme's March 7, 2011 Schedule 14D-9 for a complete and accurate description of its contents; and otherwise denies the allegations contained in Paragraph 186 of the Second Amended Complaint.

187. Refers to the CVR Agreement for a complete and accurate description of its contents; avers that the allegations in Paragraph 187 of the Second Amended Complaint constitute legal conclusions to which no response is required; and otherwise denies the allegations contained in Paragraph 187.

188. Refers to the CVR Agreement for a complete and accurate description of its contents; and otherwise denies the allegations contained in Paragraph 188 of the Second Amended Complaint.

189. Refers to the CVR Agreement for a complete and accurate description of its contents; avers that the allegations in Paragraph 189 of the Second Amended Complaint constitute legal conclusions to which no response is required; and otherwise denies the allegations contained in Paragraph 189.

190. Refers to the Consent Decree and the CVR Agreement for a complete and accurate description of their contents; and otherwise denies the allegations contained in Paragraph 190 of the Second Amended Complaint.

191. Refers to the CVR Agreement for a complete and accurate description of its contents; avers that the allegations in Paragraph 191 of the Second Amended Complaint constitute legal conclusions to which no response is required; and otherwise denies the allegations contained in Paragraph 191.

192. Denies the allegations contained in Paragraph 192 of the Second Amended Complaint.

193. Denies the allegations contained in Paragraph 193 of the Second Amended Complaint.

194. Denies the allegations contained in Paragraph 194 of the Second Amended Complaint.

195. Refers to the transcript of Sanofi's July 28, 2011 investor call for a complete and accurate description of its contents; and otherwise denies the allegations contained in Paragraph 195 of the Second Amended Complaint.

196. Refers to the CVR Agreement for a complete and accurate description of its contents; and otherwise denies the allegations contained in Paragraph 196 of the Second Amended Complaint.

197. Refers to the Merger Agreement for a complete and accurate description of its contents; and otherwise denies the allegations contained in Paragraph 197 of the Second Amended Complaint.

198. Avers that the allegations contained in Paragraph 198 of the Second Amended Complaint constitute a legal conclusion to which no response is required; and otherwise denies the allegations contained in Paragraph 198.

199. Denies the allegations contained in Paragraph 199 of the Second Amended Complaint.

200. Denies the allegations contained in Paragraph 200 of the Second Amended Complaint.

201. Denies the allegations contained in Paragraph 201 of the Second Amended Complaint.

202. Denies the allegations contained in Paragraph 202 of the Second Amended Complaint.

203. Admits that Mr. Canute left Genzyme in July 2011 and was replaced by Bill Aitchison, that Mr. Aitchison served as Senior Vice President of Global Industrial Operations at Sanofi Pasteur before joining Genzyme, and that, in that role, Mr. Aitchison interacted with the FDA; and otherwise denies the allegations contained in Paragraph 203 of the Second Amended Complaint.

204. Denies the allegations contained in Paragraph 204 of the Second Amended Complaint.

205. Denies the allegations contained in Paragraph 205 of the Second Amended Complaint.

206. Denies the allegations contained in Paragraph 206 of the Second Amended Complaint.

207. Refers to Sanofi's February 8, 2012 Press Release for a complete and accurate description of its contents; and otherwise denies the allegations contained in Paragraph 207 of the Second Amended Complaint.

208. Denies the allegations contained in Paragraph 208 of the Second Amended Complaint.

209. Admits that Pierre Fourier presented a keynote address in September 2010 at the BPI Conference on global vaccine production challenges, that Sanofi introduced the KITE initiative in 2008, that Sanofi acquired a majority stake in Shantha Biotechnics in 2009, that Sanofi issued a press release on May 5, 2009 announcing the launch of the BIOLAUNCH project, and, that, in July 2010, Biolex Therapeutics, Inc. and Merial Ltd., a subsidiary of Sanofi, announced that they had entered into a research and development collaboration to produce veterinary vaccines; refers to the May 5, 2009 Press Release for a complete and accurate description of its contents; and otherwise denies the allegations contained in Paragraph 209 of the Second Amended Complaint.

210. Admits that a single-use bioreactor is a disposable bioreactor; denies knowledge or information sufficient to form a belief as to the contents of an unnamed "industry

publication;" and otherwise denies the allegations contained in Paragraph 210 of the Second Amended Complaint.

211. Refers to Dr. Jean-Marc Guillaume's June 7, 2011 presentation entitled "BioProcess Product Management" for a complete and accurate description of its contents; and otherwise denies the allegations contained in Paragraph 211 of the Second Amended Complaint.

212. Refers to Dr. Joseph C. Frantz's November 12, 2010 presentation entitled "Effect of Entrained Air on Automated Visual Inspection of a Virus Vaccine" for a complete and accurate description of its contents; and otherwise denies the allegations contained in Paragraph 212 of the Second Amended Complaint.

213. Denies the allegations contained in Paragraph 213 of the Second Amended Complaint.

214. Admits that Genzyme used a microcarrier perfusion technology platform; denies knowledge or information sufficient to form a belief as to the allegations contained in the first sentence of Paragraph 214 of the Second Amended Complaint, which purports to quote unidentified sources; and otherwise denies the allegations contained in Paragraph 214.

215. Admits that, during the period 2010-2012, Genzyme considered continuous manufacturing technology; denies knowledge or information sufficient to form a belief as to the allegations contained in the first sentence of Paragraph 215 of the Second Amended Complaint, which purport to quote unidentified sources; and otherwise denies the allegations contained in Paragraph 215.

216. Refers to Sanofi's July 28, 2011 Press Release for a complete and accurate description of its contents; and otherwise denies the allegations contained in Paragraph 216 of the Second Amended Complaint.

217. Refers to Sanofi's July 28, 2011 Press Release for a complete and accurate description of its contents; and otherwise denies the allegations contained in Paragraph 217 of the Second Amended Complaint.

218. Denies the allegations contained in Paragraph 218 of the Second Amended Complaint.

219. Denies the allegations contained in Paragraph 219 of the Second Amended Complaint.

220. Admits that the FDA approved the Framingham Facility for the production of Fabrazyme® in January 2012; refers to Sanofi's January 24, 2012 Press Release for a complete and accurate description of its contents; and otherwise denies the allegations contained in Paragraph 220 of the Second Amended Complaint.

221. Denies the allegations contained in Paragraph 221 of the Second Amended Complaint.

222. Denies the allegations contained in Paragraph 222 of the Second Amended Complaint.

223. Refers to Sanofi's July 28, 2011 Press Release for a complete and accurate description of its contents; and otherwise denies the allegations contained in Paragraph 223 of the Second Amended Complaint.

224. Refers to Sanofi's July 28, 2011 Press Release and the transcript of Sanofi's November 3, 2011 earnings call for a complete and accurate description of their contents; and otherwise denies the allegations contained in Paragraph 224 of the Second Amended Complaint.

225. Admits that validation runs may be included as commercial stock; and otherwise denies the allegations contained in Paragraph 225 of the Second Amended Complaint.

226. Denies the allegations contained in Paragraph 226 of the Second Amended Complaint.

227. Refers to Sanofi's July 28, 2011 Press Release and the transcript of Sanofi's November 3, 2011 earnings call for a complete and accurate description of their contents; and otherwise denies the allegations contained in Paragraph 227 of the Second Amended Complaint.

228. Denies the allegations contained in Paragraph 228 of the Second Amended Complaint.

229. Refers to Plaintiff's December 9, 2016 letter (the "December 9 Letter") for a complete and accurate description of its contents; and otherwise denies the allegations contained in Paragraph 229 of the Second Amended Complaint.

230. Refers to the December 9 Letter for a complete and accurate description of its contents; and otherwise denies the allegations contained in Paragraph 230 of the Second Amended Complaint.

231. Refers to Sanofi's January 12, 2017 Letter (the "January 12 Letter") for a complete and accurate description of its contents; and otherwise denies the allegations contained in Paragraph 231 of the Second Amended Complaint.

232. Denies the allegations contained in Paragraph 232 of the Second Amended Complaint.

233. Denies the allegations contained in Paragraph 233 of the Second Amended Complaint.

234. Denies the allegations contained in Paragraph 234 of the Second Amended Complaint.

235. Refers to the CVR Agreement and the September Order for a complete and accurate description of their contents; avers that to the extent the allegations contained in Paragraph 235 of the Second Amended Complaint relate to claims and/or theories that have been dismissed by the Court, no response is required to such allegations; and otherwise denies the allegations contained in Paragraph 235.

236. Refers to the CVR Agreement for a complete and accurate description of its contents; avers that to the extent the allegations contained in Paragraph 236 of the Second Amended Complaint relate to claims and/or theories that have been dismissed by the Court, no response is required to such allegations; and otherwise denies the allegations contained in Paragraph 236.

237. Refers to Plaintiff's December 15 Letter (the "December 15 Letter") for a complete and accurate description of its contents; avers that to the extent the allegations contained in Paragraph 237 of the Second Amended Complaint relate to claims and/or theories that have been dismissed by the Court, no response is required to such allegations; and otherwise denies the allegations contained in Paragraph 237.

238. Refers to the December 15 Letter for a complete and accurate description of its contents; avers that to the extent the allegations contained in Paragraph 238 of the Second Amended Complaint relate to claims and/or theories that have been dismissed by the Court, no response is required to such allegations; and otherwise denies the allegations contained in Paragraph 238.

239. Refers to the January 12 Letter for a complete and accurate description of its contents; avers that to the extent the allegations contained in Paragraph 239 of the Second Amended Complaint relate to claims and/or theories that have been dismissed by the Court, no response is required to such allegations; and otherwise denies the allegations contained in Paragraph 239 of the Amended Complaint.

240. Avers that to the extent the allegations contained in Paragraph 240 of the Second Amended Complaint relate to claims and/or theories that have been dismissed by the Court, no response is required to such allegations; and otherwise denies the allegations contained in Paragraph 240.

241. Avers that to the extent the allegations contained in Paragraph 241 of the Second Amended Complaint relate to claims and/or theories that have been dismissed by the Court, no response is required to such allegations; and otherwise denies the allegations contained in Paragraph 241.

242. Avers that to the extent the allegations contained in Paragraph 242 of the Second Amended Complaint relate to claims and/or theories that have been dismissed by the Court, no response is required to such allegations; and otherwise denies the allegations contained in Paragraph 242.

243. Denies knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 243 of the Second Amended Complaint.

244. Refers to the CVR Agreement and Plaintiff's December 19, 2016 Letter (the "December 19 Letter") for a complete and accurate description of their contents; and otherwise denies the allegations contained in Paragraph 244 of the Second Amended Complaint.

245. Refers to the January 12 Letter for a complete and accurate description of its contents; and otherwise denies the allegations contained in Paragraph 245 of the Second Amended Complaint.

246. Denies the allegations contained in Paragraph 246 of the Second Amended Complaint.

247. Denies the allegations contained in Paragraph 247 of the Second Amended Complaint.

CAUSES OF ACTION

COUNT I
BREACH OF CONTRACT FOR FAILURE TO USE DILIGENT EFFORTS TO MEET THE APPROVAL MILESTONE

248. Repeats and realleges its responses to Paragraphs 1-247 of the Second Amended Complaint as if fully set forth herein.

249. Refers to the CVR Agreement for a complete and accurate description of its contents; and otherwise denies the allegations contained in Paragraph 249 of the Second Amended Complaint.

250. Denies the allegations contained in Paragraph 250 of the Second Amended Complaint.

251. Denies the allegations contained in Paragraph 251 of the Second Amended Complaint.

COUNT II
BREACH OF CONTRACT FOR FAILURE TO USE DILIGENT EFFORTS TO MEET THE PRODUCT SALES MILESTONES

252. Repeats and realleges its responses to Paragraphs 1-247 of the Second Amended Complaint as if fully set forth herein.

253. Refers to the CVR Agreement for a complete and accurate description of its contents; avers that to the extent the allegations contained in Paragraph 253 of the Second Amended Complaint relate to claims and/or theories that have been dismissed by the Court, no response is required to such allegations; and otherwise denies the allegations contained in Paragraph 253.

254. Avers that to the extent the allegations contained in Paragraph 254 of the Second Amended Complaint relate to claims and/or theories that have been dismissed by the Court, no response is required to such allegations; and otherwise denies the allegations contained in Paragraph 254.

255. Avers that to the extent the allegations contained in Paragraph 255 of the Second Amended Complaint relate to claims and/or theories that have been dismissed by the Court, no response is required to such allegations; and otherwise denies the allegations contained in Paragraph 255.

COUNT III
BREACH OF THE IMPLIED COVENANT OF GOOD FAITH AND FAIR DEALING

256. Repeats and realleges its responses to Paragraphs 1-247 of the Second Amended Complaint as if fully set forth herein.

257. Avers that Count III of the Second Amended Complaint, for Sanofi's alleged breach of the implied covenant of good faith and fair dealing, was dismissed by the Court and, thus, no response to the allegations contained in Paragraph 257 of the Second Amended Complaint is required (to the extent a response is required, Sanofi denies such allegations).

258. Avers that Count III of the Second Amended Complaint, for Sanofi's alleged breach of the implied covenant of good faith and fair dealing, was dismissed by the Court

and, thus, no response to the allegations contained in Paragraph 258 of the Second Amended Complaint is required (to the extent a response is required, Sanofi denies such allegations).

259. Avers that Count III of the Second Amended Complaint, for Sanofi's alleged breach of the implied covenant of good faith and fair dealing, was dismissed by the Court and, thus, no response to the allegations contained in Paragraph 259 of the Second Amended Complaint is required (to the extent a response is required, Sanofi denies such allegations).

COUNT IV
DECLARATORY JUDGMENT AGAINST SANOFI REQUIRING REIMBURSEMENT OF TRUSTEE FEES AND EXPENSES

260. Admits that Plaintiff purports to describe the relief sought in the Supplemental Complaint; Sanofi repeats and realleges its Answer to the Supplemental Complaint (ECF No. 64).

COUNT V
DECLARATORY JUDGMENT AGAINST SANOFI FOR FAILURE TO COMPLY WITH TRUSTEE'S REQUESTS PURSUANT TO SECTIONS 4.2(f) AND 5.4(b) OF THE CVR AGREEMENT

261. Repeats and realleges its responses to Paragraphs 1-247 of the Second Amended Complaint as if fully set forth herein.

262. Refers to the CVR Agreement for a complete and accurate description of its contents; avers that to the extent the allegations contained in Paragraph 262 of the Second Amended Complaint relate to claims and/or theories that have been dismissed by the Court, no response is required to such allegations; and otherwise denies the allegations contained in Paragraph 262.

263. Refers to the December 9 Letter and December 15 Letter for a complete and accurate description of their contents; avers that to the extent the allegations contained in Paragraph 263 of the Second Amended Complaint relate to claims and/or theories that have been

dismissed by the Court, no response is required to such allegations; and otherwise denies the allegations contained in Paragraph 263.

264. Refers to January 12 Letter for a complete and accurate description of its contents; avers that to the extent the allegations contained in Paragraph 264 of the Second Amended Complaint relate to claims and/or theories that have been dismissed by the Court, no response is required to such allegations; and otherwise denies the allegations contained in Paragraph 264.

265. Denies the allegations contained in Paragraph 265 of the Second Amended Complaint.

266. Denies the allegations contained in Paragraph 266 of the Second Amended Complaint.

267. Avers that the allegations contained in Paragraph 267 of the Second Amended Complaint constitute legal conclusions to which no response is required.

268. Admits that Plaintiff purports to describe the relief sought in Count V of the Second Amended Complaint; and otherwise avers that the allegations contained in Paragraph 268 of the Second Amended Complaint do not constitute allegations to which a response is required.

COUNT VI
DECLARATORY JUDGMENT AGAINST SANOFI FOR FAILURE TO COMPLY WITH THE TRUSTEE'S REQUEST, ON BEHALF OF ACTING HOLDERS, PURSUANT TO SECTION 7.6(a) OF THE CVR AGREEMENT

269. Repeats and realleges its responses to Paragraphs 1-247 of the Second Amended Complaint as if fully set forth herein.

270. Refers to the CVR Agreement for a complete and accurate description of its contents; and otherwise denies the allegations contained in Paragraph 270 of the Second Amended Complaint.

271. Refers to the December 19 Letter for a complete and accurate description of its contents; denies knowledge or information sufficient to form a belief as to whether Plaintiff was acting "at the request of Acting Holders;" and otherwise denies the allegations contained in Paragraph 271 of the Second Amended Complaint.

272. Refers to the January 12 Letter for a complete and accurate description of its contents; and otherwise denies the allegations contained in Paragraph 272 of the Second Amended Complaint.

273. Denies the allegations contained in Paragraph 273 of the Second Amended Complaint.

274. Denies the allegations contained in Paragraph 274 of the Amended Complaint.

275. Avers that the allegations contained in Paragraph 275 of the Second Amended Complaint constitute legal conclusions to which no response is required.

276. Admits that Plaintiff purports to describe the relief sought in Count VI of the Second Amended Complaint; and otherwise avers that the allegations contained in Paragraph 276 of the Second Amended Complaint do not constitute allegations to which a response is required.

COUNT VII
BREACH OF CONTRACT FOR FAILURE TO USE COMMERCIALLY REASONABLE EFFORTS TO MEET THE PRODUCTION MILESTONE ON A TIMELY BASIS

277. Repeats and realleges its responses to Paragraphs 1-247 of the Second Amended Complaint as if fully set forth herein.

278. Refers to the CVR Agreement for a complete and accurate description of its contents; and otherwise denies the allegations contained in Paragraph 278 of the Second Amended Complaint.

279. Denies the allegations contained in Paragraph 279 of the Second Amended Complaint.

280. Denies the allegations contained in Paragraph 280 of the Second Amended Complaint.

* * *

GENERAL DENIAL

Except as otherwise stated in Paragraphs 1 through 280 above, Sanofi denies each and every allegation directed at it in Paragraphs 1 through 280 of the Second Amended Complaint, including, without limitation, the introductory paragraph, headings, subheadings, and footnotes contained therein, and specifically denies liability to Plaintiff or any CVR Holder. Allegations in the Second Amended Complaint to which no responsive pleading is required shall be deemed denied. Sanofi expressly reserves its right to amend and/or supplement this Answer, including, but not limited to, the defenses and affirmative defenses set forth herein.

DEFENSES AND AFFIRMATIVE DEFENSES

Without admitting or denying any of the allegations of the Second Amended Complaint and without admitting or suggesting that Sanofi bears the burden of proof on any of the following issues, as separate and independent defenses and/or affirmative defenses, Sanofi states as follows:

1. The Second Amended Complaint fails to state a claim upon which relief can be granted.

2. Sanofi has performed all obligations it was required to perform under the CVR Agreement that form the basis for Plaintiff's claims and, thus, is not liable for the claims asserted.

3. Plaintiff's claims are barred because any and all actions taken by Sanofi were, at all times, lawful, proper and consistent with its duties and obligations, including those set forth in the CVR Agreement (including, but not limited to, the "Diligent Efforts" and "commercially reasonable efforts" provisions contained therein).

4. Plaintiff's claims are barred because Plaintiff has not suffered any injury or harm as a result of any action or inaction by Sanofi.

5. Plaintiff's damages, if any, are speculative and not recoverable.

6. The relief sought by Plaintiff is barred by the doctrines of laches, waiver, equitable estoppel, in pari delicto, unclean hands and/or other related equitable doctrines.

7. Plaintiff's claims are barred by the statute of limitations.

8. Plaintiff's claims are barred, and/or Plaintiff is precluded from recovery of any damages in respect of its claims, because Plaintiff violated the implied covenant of good faith and fair dealing with respect to, among other things, the December Letters.

9. Plaintiff's claims are barred, and/or Plaintiff is precluded from recovery of any damages in respect of its claims, because Plaintiff has acted in bad faith with respect to, among other things, the December Letters.

10. Plaintiff's claims are barred by Plaintiff's own actions, omissions, negligence and/or assumption of the risk.

11. Plaintiff's claims are barred to the extent Plaintiff failed to mitigate any alleged injury or damages.

12. Plaintiff's claims are barred because Sanofi did not breach, and Plaintiff cannot prove that Sanofi breached, the CVR Agreement.

13. Plaintiff's claims are barred for the reasons set forth in the September Order.

14. Plaintiff's claims are barred because Sanofi at all times acted in accordance with commercial and industry standards.

15. Sanofi reserves the right to assert additional defenses and/or affirmative defenses as may be appropriate.

WHEREFORE, Sanofi prays for judgment as follows:

1. For a judgment and decree dismissing the Second Amended Complaint with prejudice;

2. For a judgment and decree awarding Sanofi's costs, including attorneys' fees; and

3. For such other and further relief as the Court may deem just and proper under the circumstances.

Dated: New York, New York
September 29, 2017

Respectfully submitted,

/s/ John A. Neuwirth

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